201-14688

NCIC HPV
Sent by: Nguyet Phan

08/22/03 10:31 AM

To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Environmental Defense comments on the Chloronitrobenzenes Category

Richard_Denison@environmentaldefense.org on 08/21/2003 03:43:34 PM

To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, dalede@solutia.com
cc: lucierg@msn.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on the Chloronitrobenzenes Category

(Submitted via Internet 8/21/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, lucierg@msn.com and dalede@solutia.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for the Chloronitrobenzenes Category.

The test plan and robust summaries for the chloronitrobenzenes was prepared by Solutia, Inc. There are three chemicals in the proposed category: o-chloronitrobenzene (CAS # 88-73-3), m-chloronitrobenzene (CAS # 121-73-3) and p-chloronitrobenzene (CAS # 100-00-5). This is the last of a series of three test plans prepared by Solutia, Inc. on a series of related chemicals; the other two were the mononitroanilines and 4-nitrophenol. We commend the sponsor for resisting the temptation to lump the mononitroanilines and 4-nitrophenol together with the chloronitrobenzenes as a single category. We agree that the proposed chloronitrobenzene category is scientifically justified and we support it.

Considerable data exist for the three chloronitrobenzenes and the sponsor proposes to use limited read-across methods to fulfill the remaining required SIDS endpoints, hence maintaining that no additional studies are needed. We agree with the proposed test plan but we are concerned with some of the risk assessment statements made in the test plan as they relate to relative potency and margin of safety analysis. Specific comments are as follows:

1. According to the sponsor, the chloronitrobenzenes are manufactured by a single producer in the U.S. at a single manufacturing site in an essentially closed and continuous process. A TLV of 0.1 ppm has been established for p-chloronitrobenzene (PCNB) -- indicative of the significant toxicity of these chemicals. Allowable levels are 1.5 ppm for m-chloronitrobenzene (MCNB) and o-chloronitrobenzene (OCNB). The sponsor states that practices are in place to minimize worker exposure, but those practices have not been described. Also, since all proposed category members are expected to act similarly, levels of worker exposure to the three individual chloronitrobenzenes should be aggregated in assessing risks from such exposures.

2. The chloronitrobenzenes are important intermediates in the synthesis of

numerous industrial chemicals such as dyes, pigments, pesticides, veterinary pharmaceuticals and water treatment chemicals. The sponsor states that there are no known consumer uses of category members and that emissions are minimal. However, no information was provided on environmental releases (air or water) during the production of different products. It seems plausible that the emissions for some uses of the chloronitrobenzenes might be greater than it is for others. While some of these potential releases would likely come from the facilities of Solutia's customers for these chemicals, we encourage the sponsor to provide environmental release data if available for the different uses of the chloronitrobenzenes.

3. Many of the studies on ecotoxicity endpoints presented in the robust summaries were not conducted under GLP, but they do seem to be well done and read-across is not used to fulfill ecotoxicity endpoints, so we agree with the sponsor that no additional studies are needed.

4. The data provided for mammalian toxicity endpoints are adequate to support the proposed read-across to fulfill the repeat dose, reproductive and developmental endpoints for MCNB.

5. The sponsor states that PCNB is the most toxic of the chloronitrobenzenes; however, this statement is not supported by data presented in the robust summaries. For example, all proposed members induce methemoglobinemia and rat acute toxicity data show that MCNB is the most toxic, followed by OCNB and then PCNB. Moreover, inhalation repeat dose studies indicate no difference in the NOEL for OCNB and PCNB. These studies also show that OCNB induces epithelial hyperplasia of the respiratory tract at low doses, whereas PCNB does not cause this effect even at high doses. Mutagenicity studies indicate that OCNB and PCNB are equipotent. Therefore, the data indicate that PCNB cannot be considered the most toxic of the chloronitrobenzenes. Rather, in our view, rank ordering done for purposes of read-across needs to reflect the actual toxicity values for a given endpoint for the category members. It should also be assumed that any effect caused by any of the proposed category members will occur for all members.

6. The sponsor states that there is an adequate margin of safety for occupational exposures to the chloronitrobenzenes. This is a risk assessment statement and there is inadequate data presented in the test plan and robust summaries to justify it. We also note that inhalation repeat dose studies on OCNB indicate that hyperplasia of the respiratory epithelium and methemoglobinemia are occurring at a dose of 1.1 ppm -- an exposure level quite close to the TLV. This finding does not indicate an adequate margin of safety.

Thank you for this opportunity to comment.

George Lucier, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense